DEPARTMENT OF HEALTH AND HUMAN SERVICES

95074d

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751
Telephone: 407-475-4731

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

# WARNING LETTER

**FLA-05-05**

November 2, 2004

Ms. Alice R. Barr
Chief Executive Officer
Blood Net USA, Inc.
3200 Lakeland Hills Blvd.
Lakeland, Florida 33805-2271

Dear Ms. Barr:

The Food and Drug Administration (FDA) inspected your licensed full service blood bank and contract testing laboratory located at the above address on 8/09/2004-9/1/2004. The inspection revealed numerous deviations from the Current Good Manufacturing Practice (CGMP) regulations and Additional Standards for Blood and Blood Components, set forth in Title 21, Code of Federal Regulations, (21 CFR), Parts 606, 610, and 640. These deviations cause your blood product to be adulterated within the meaning of section 501(a) (2) (B) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviations documented on the form FDA-483 issued and discussed with you at the conclusion of the inspection include:

1. Failure to ensure that whole blood and plasmapheresis donors meet suitability criteria as required by 21 CFR 640.3. Specifically,

   a. Your firm failed to permanently defer Apheresis donor #[redacted] and Whole Blood donor #[redacted], both of whom previously reported positive tests for HIV (FDA 483 #2).

   b. Your firm failed to defer donor #[redacted] who had a test for syphilis, for which there was no indication whether the test results were negative or positive, or was treated for syphilis / gonorrhea in the past year (FDA 483 #2).

   c. Your firm failed to defer donor #[redacted] who was under doctor's care, for an undiagnosed stomach disorder, at the time of screening (FDA 483 #2).

   d. Your firm failed to conduct adequate evaluations of the medications that donors were currently taking, and failed to document the status of at least six donors with diabetes prior to acceptance (FDA 483 #2).

2. Failure to ensure that each donor was in good health as required by 21 CFR 640.3(b)(3). Specifically, apheresis donor #[redacted] was inappropriately accepted for donation on 2/9/04 after three hemoglobin tests were conducted which obtained values of 11.6 on the first test, 12.2 on a retest and value of 13.4 on a third test (FDA 483 #3).

3. Failure to ensure that the personnel responsible for the processing of blood or blood components have adequate training and experience, including professional training as necessary to assure competent performance of their assigned functions, and to ensure that the final product has the safety, purity, potency, identity and effectiveness it purports or is represented to possess as required by 21 CFR 606.20(b). For example,

    a. There is no documentation that an employee who was observed processing leuko-reduced red blood cells on 8/27/04 was trained in her assigned duties (FDA 483 #9).

    b. This same employee did not follow written procedures in disconnecting the unit from the filter in that the transfer and unit tubing were not sealed in three places and then cut at the middle seal in accordance with the written procedures (FDA 483 #9).

4. Failure to take appropriate action when a donor tests repeatedly reactive for antibody to human immunodeficiency virus (HIV) as required by 21 CFR 610.46(a)(1). For example,

    a. A donor of whole blood collected on 2/17/04 under unit #[redacted] tested HIV 1-2 reactive in screening, and there was no documentation on file that your firm notified the consignee of the fresh frozen plasma processed from a prior whole blood donation on 12/02/03 (FDA 483 #6) .

    b. A donor of blood collected on 8/22/03 under unit #[redacted] tested HIV reactive in screening test performed 8/25/03. The consignee of the plasma from a prior whole blood donation on 2/7/03 was not notified until 8/29/03 (FDA 483 #6).

5. Failure to submit a biological product deviation report within 45 days from the date you acquired information suggesting that a reportable event occurred as required by 21 CFR 606.171(c). Specifically,

    a. Your firm failed to submit a Blood Product Deviation (BPD) report for an event that occurred on 5/6/03 when your firm distributed platelet unit #[redacted] for transfusion labeled as CMV negative but the unit was never tested for CMV (FDA 483 #10).

    b. Failure to submit a BPD report for an event that occurred on 1/15/03 which allowed an ineligible donor to donate blood (FDA 483 #10).

    c. BPD #2004-008 discovered on 12/04/03 was not reported to FDA until 2/20/04 (FDA 483 #10).

6. Failure to prepare and maintain written reports of the investigation of adverse reactions, including conclusions and follow up as required by 21 CFR 606.170(a). For example, 3 of 10 donor reaction reports that were reviewed were found to be inappropriately classified as moderate when the reactions should have been classified as severe according to your firm's written procedures (FDA 483 #7).

7. Failure to perform a thorough investigation and make a record of the conclusion and follow-up of an unexplained discrepancy as required by 21 CFR 606.100(c). Specifically,

    a. Your firm failed to conduct a thorough internal investigation report in accordance with written procedures regarding the labeling and release of 5 units of whole blood that tested NAT reactive (FDA 483 #4)

    b. Your firm failed to conduct a thorough internal investigation report in accordance with written procedures regarding the premature removal of a deferral code (FDA 483 # 4).

8. Failure to establish and maintain written procedures which include all steps to be followed in the collection, processing, compatibility testing, storage, and distribution of blood and blood components for transfusion and further manufacturing purposes as required by 21 CFR 606.100(b).

    a. Your written procedure for HIV lookback failed to include notification of consignees for blood and blood components of a donor who has tested repeatedly reactive for antibody to human immunodeficiency virus (FDA 483 # 8).

    b. Your firm does not have a written eligibility procedure to qualify donors who have reported a previous test for the AIDS virus and have been told not to donate by another blood bank (FDA 483 #5).

    c. Your firm's Donor Eligibility procedure is inadequate in that, the procedure does not list actions to take if the donor answers "no" to not feeling well and healthy today and the procedure does not provide specifics on evaluating donors with a history of surgery or major illness in the past year (FDA 483 #5).

9. Failure to maintain schedules and procedures for equipment maintenance and calibration as required by 21 CFR 606.100(b)(15). Specifically, there is no written procedure for the maintenance of the Composeal Universal sealer used in the preparation of leuko-reduced blood components or for cleaning of the device after a blood spill (FDA 483 #11).

10. Failure to establish written distribution and receipt procedures which include a system by which the distribution or receipt of each unit can be readily determined to facilitate its recall, if necessary, as required by 21 CFR 606.165(a) (FDA 483 # 12).

We acknowledge receipt of your written response, dated September 22, 2004, submitted to this office in response to the FDA 483 issued to you at the conclusion of our inspection on 8/9-9/1/04. We have reviewed this response and made it part of the official file. The response appears inadequate in that you did not provide supporting documentation sufficient to permit FDA to evaluate the stated corrections.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your blood bank facility and contract testing laboratory. It is your responsibility to ensure that your blood bank facility is in compliance with all applicable requirements of 21 CFR Part 606, 610, and 640, and the Act. You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to do so may result in regulatory or administrative actions without further notice. Possible actions include, but are not limited to, license suspension, seizure and/or injunction.

You should notify this office in writing, within (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violation(s), including an explanation of each step taken to prevent recurrence of similar violations and supporting documentation sufficient to permit FDA to evaluate the corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to the Food and Drug Administration, Attention: Virginia L. Meeks, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, FL 35271. If you have questions regarding any issue in this letter, please contact Ms. Meeks at (407) 475-4731.

Sincerely,

Emma R. Singleton
Director, Florida District